



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/039,753 | 01/02/2002 | Stanley Hazen | 26473/04177 | 9142 |

24024 7590 03/24/2005
CALFEE HALTER & GRISWOLD, LLP
800 SUPERIOR AVENUE
SUITE 1400
CLEVELAND, OH 44114

EXAMINER

NOLAN, PATRICK J

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/039,753

Applicant(s)

HAZEN ET AL.

Examiner

Patrick J. Nolan

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 2-6, 11-22 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7-10, 23 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/24/02, 8/12/02, 8/5/02, 4/22/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1644

1. Claims 1-27 are pending.
2. Applicant's election with traverse of Group I claims 1-16, now including newly added claims 23-27 and species MPO mass, in the reply filed on 1-6-05 is acknowledged. The traversal is on the ground(s) that it would be unduly burdensome for the Examiner to examine. This is not found persuasive because prior art on one invention would not necessarily be prior art on the other.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 2-6, 11-22 and 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1-6-05.

It is noted that claim 16 is included in the withdrawn claims. Upon further review by the Examiner, claim 16 is drawn to detecting both MPO mass or activity and detecting MPO generated oxidation products. Since the claim reads upon detecting a combination of compounds, it is not included in the claims to be examined since applicant elected a single compound, MPO mass to be examined as the elected species.

Further, Applicant is notified that upon a finding that a determination of MPO mass in characterizing a test subjects risk for developing or having cardiovascular disease is free of the prior art, the Examiner will move on to search the next species of the claimed invention.

4. Claims 1, 7-10, 23 and 25-27 are currently being examined in the present Office Action.
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 7, 9, 23, 26 and 27 rejected under 35 U.S.C. 102(b) as being anticipated by Daugherty et al (Reference AN on the IDS submitted 8-12-02).

Art Unit: 1644

Daugherty et al., teaches the detection of an increase of MPO mass by immuno-histochemistry in patients with atherosclerotic lesions that occurred due to aortic aneurysm, amputation or carotid endarectomy compared with an aorta from a normal young organ donor (see figure 4 in particular). Since, atherosclerotic plaques are derived from blood, the claimed invention is anticipated. Claim 26 and Claim 27 are included because patients that have surgery for atherosclerotic lesion removal undergo further medical intervention because they are generally considered at risk for experiencing an acute adverse cardiovascular event.

If applicant was to amend the base claim to further clarify what is intended by a blood derivative, the rejection may be obviated.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly added claim 25 has no written support in the originally filed claims or specification. The specification has been reviewed and support has been found for "an apparently healthy subject" in regards to those subjects that would make up the control subjects, not the test subjects.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

Art Unit: 1644

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 7-10, 23 and 26-27 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-10 and 16-17 of copending Application No. 10/972,058. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '058 application is drawn to a species of determining cardiovascular disease, chest pain by detecting MPO mass using immunoassays, while the instant application is drawn to the genus of any cardiovascular event by detecting MPO mass using immunoassays and as such the species anticipates the genus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. It is noted that references AJ on the IDS's filed 8-21-02 and 4-22-04 have been considered but have been crossed out since search reports are appropriate for printing on the face of an issued US Patent.

12. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

Art Unit: 1644

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

A handwritten signature in black ink, appearing to read "Patrick J. Nolan".

Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

March 19, 2005